(Billing Code: 4150-31)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Parag Patel, D.O., Advocate Health Care Network d/b/a Advocate Health Care: Based on an investigation conducted by Advocate Health Care Network d/b/a Advocate Health Care (Advocate Health Care) and additional analysis conducted by ORI in its oversight review, ORI and Advocate Health Care found that Dr. Parag Patel, Cardiologist, Department of Medicine, Advocate Health and Hospitals Corporation d/b/a Advocate Lutheran General Hospital, Park Ridge, Illinois, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant U01 HL089458.

ORI and Advocate Health Care found that the Respondent engaged in research misconduct by directing or intimidating fellows and others to influence left ventricular ejection fraction (LVEF)

scores of ≤ 35% and requesting attending physicians to reassess scores of LVEF to be reported as ≤ 35% for research subjects after being diagnosed with acute myocardial infarction, thereby causing and being responsible for falsification of research records. These falsifications made subjects eligible for enrollment into the "Vest Prevention of Early Sudden Death Trial" (VEST) when they otherwise may not have been eligible.

The Respondent, Advocate Health Care, and the U.S. Department of Health and Human Services (HHS) want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter. Respondent neither admits nor denies ORI's and Advocate Health Care's findings of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent.

Dr. Patel has voluntarily agreed for a period of two (2) years, beginning on February 21, 2014:

(1) to have any U.S. Public Health Service (PHS)-supported research in which he is involved be supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research

contribution as outlined below; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that the requirements for Respondent's supervision plan are as follows:

- a committee of two to three qualified physicians at the institution's discretion, who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance; the committee will review primary data from Respondent's participation in PHS-supported research on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee's meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research contribution; and

- the committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that

the data presented in the proposed application/publication are supported by the research record;

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(3) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(4) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:

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Office of Research Integrity

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